

Project Charter

A. General Information

Provide basic information about the project including: Project Title – The proper name used to identify this project; Project Working Title – The working name or acronym that will be used for the project; Proponent Secretary – The Secretary to whom the proponent agency is assigned or the Secretary that is sponsoring an enterprise project; Proponent Agency – The agency that will be responsible for the management of the project; Prepared by – The person(s) preparing this document.

Project Title:	DCLS Laboratory Information Management System	Project Working Title:	New LIM System
Proponent Secretary:	Secretary of Administration	Proponent Agency:	Department of General Services
Prepared by:	William Eighme Wanda (Willie) Andrews		

Points of Contact

List the principal individuals who may be contacted for information regarding the project.

<i>Position</i>	<i>Title/Name/Organization</i>	<i>Phone</i>	<i>E-mail</i>
<i>Project Sponsor</i>	Assistant Bureau Director, Wanda (Willie) Andrews, DCLS	648-4480	wandrews@dgs.state.va.us
<i>Program Manager</i>	Director, Dr. James L. Pearson, DCLS	648-4480	jpearson@dgs.state.va.us
<i>Project Manager</i>	LIMS Coordinator, William Eighme	648-4480	weighme@dgs.state.va.us
<i>Proponent Cabinet Secretary</i>	Secretary Sandra Bowen	786-1201	sbowen@gov.state.va.us
<i>Proponent Agency Head</i>	Director, James T. Roberts	786-3311	jroberts@dgs.state.va.us
<i>Customer (User) Representative(s)</i>	Jim Burns - Department of Health; Larry Lawson - Department of Environmental Quality; Marvin Lawson - Department of Agriculture and Consumer Services	371-4138; 698-4108; 786-3534	jburns@vdh.state.va.us llawson@deq.state.va.us; mlawson@vdacs.state.va.us
<i>Other</i>	Application Development Manager - Technical Project Lead/Richard A. (Rick) Davis/ISS	371-2102	rdavis@dgs.state.va.us

B. Executive Summary

An Executive Summary is required when Sections C thru G of the charter are excessively long. In two or three paragraphs, provide a brief overview of this project and the contents of this document.

C. Project Purpose

Explain the business reason(s) for doing this project. The Project Purpose (the Business Problem and Project Business Objectives) is in the Project Proposal, Section B.

1. Business Problem

The Business Problem is a question, issue, or situation, pertaining to the business, which needs to be answered or resolved. State in specific terms the problem or issue this project will resolve. Often, the Business Problem is reflected as a critical business issue or initiative in the Agency's Strategic Plan or IT Strategic Plan.

As the state laboratory for the Commonwealth of Virginia, The Division of Consolidated Laboratory Services (DCLS) provides laboratory support services for a wide variety of local, state and federal law enforcement, emergency response, health and environmental protection programs. The state laboratory is at the core of the Commonwealth's public health system linking almost every facet of the health infrastructure including food safety, disease control and prevention, maternal and child health. State laboratory data are also used to monitor the quality of air we breathe, water we drink, food we eat and the soil used to grow our crops. As was most evident post 9/11, the efficacy of state laboratory is critical for a rapid response to biological and chemical agents used for illegal or terrorist activities. In evaluating DCLS's current capabilities, there is a critical need to implement a robust, integrated, comprehensive laboratory information management system (LIMS) that can securely gather, integrate, store and transmit data.

DCLS currently performs approximately 3 million scientific tests each year for citizens of the

Commonwealth and does so without an integrated public health clinical testing information system. Most areas of the laboratory still receive requests on paper and record, report and file results on paper forms. DCLS maintains a variety of database applications to maintain supply, kit and equipment inventories, sample submission and test result data. Most of these applications are antiquated, not efficient or secure and extremely labor intensive. DCLS recently purchased and installed an information management system that specifically meets the analytical needs of the Newborn Screening Program. Major customization of this system would be required for use in other analytical areas. DCLS also maintains an environmental Laboratory Information Tracking System that was built 10 years ago by DCLS staff and is limited in scope. The Newborn Screening system and the environmental information tracking system are not integrated.

The implementation of a comprehensive LIMS will enable DCLS to communicate more efficiently with local, state and federal public health facilities for the purpose of disease prevention, control and surveillance as well as emergency response. This LIMS will allow secure electronic transmission of specimen collection data and results to and from DCLS. The time required and errors caused by duplicated data entry processes will be eliminated. This LIMS will provide customers with immediate access to sample tracking information and completed results. It will facilitate the direct transfer of information from laboratory instrumentation to LIMS, again reducing data entry errors, saving labor time and allowing staff to take full advantage of current and future technologies. It will enable quality assurance/ quality control procedures to be built into the system for increased efficiency of error detection/prevention. The LIMS will allow for data archiving and ad hoc reporting. It will save DCLS personnel time and reduce potential errors in data handling. Data can be integrated and evaluated. Data can be securely transferred and entered into national databases eliminating duplicated manual data entry processes. In addition, the maintenance tasks would be reduced for DGS ISS and DCLS over the current multiple disjointed systems.

2. *Project Business Objectives*

Define the specific Business Objectives of the project that correlate to the strategic initiatives or issues identified in the Commonwealth or Agency Strategic Plan. Every Business Objective must relate to at least one strategic initiative or issue and every initiative or issue cited must relate to at least one project business objective.

<i>Commonwealth or Agency Strategic Plan – Initiative or Critical Issue</i>	<i>Project Business Objectives</i>
CUSTOMER SATISFACTION: Providing proactive customer service that is results-oriented; developing a marketing and communications plan for customers.	<p>Through improved capabilities for data archiving and ad hoc reporting, the LIMS will enable DCLS to capture and provide its customers with real time access to data that is essential for public health analysis and decision-making.</p> <p>The DCLS LIMS will provide improved customer service through increased access to electronic collection laboratory information, kit requests, sample forms and testing results.</p> <p>By eliminating multiple databases, the DCLS LIMS will enable the state laboratory to serve as a centralized data resource for its customers.</p>
PROGRAM EFFICIENCY: Make it easier to do business with DGS; streamline work processes to shorten response time; plan for contingencies; complete projects on budget, on time; use staffing alternatives.	<p>The DCLS LIMS will result in improved efficiencies and product quality by eliminating duplicated data entry processes for DCLS and its customers. The capability to pre-log samples will improve speed and accuracy in sample accessioning.</p> <p>Response times will be shortened through real time access to kit inventory and testing information. Providing customer access to laboratory information will reduce timely phone communication.</p> <p>Integrating data will provide customers with better surveillance information.</p> <p>The use of software tools such as bar-coding, optical scanners and instrument interfacing will result in improved efficiency and accuracy.</p>
PROGRAM EFFECTIVENESS: Describe services & how to access them to customers; expedite delivery of products/services; evaluate products/services & their delivery; understand customers' needs more fully.	<p>The LIMS will enable DCLS to provide secure, encrypted data to public health customers and partners at the federal, state and local level. Providing secure electronic data transfers will improve patient confidentiality as well as emergency response time.</p> <p>The DCLS LIMS will provide management with better tools to evaluate productivity, service delivery, use of man-power and laboratory costs.</p>

<p>ORGANIZATION DEVELOPMENT/INNOVATION: Staff appropriately to meet customers' needs and to provide emergency response; expand technology in the laboratory.</p>	<p>The DCLS LIMS will take full advantage of current and future technologies. The system will incorporate the use of tools such as bar-coding, instrument interfacing and web-based technology to create an efficient and flexible application.</p> <p>The DCLS LIMS will provide the capability to quickly adapt the laboratory's business rules to respond to public health emergencies and to meet the changing needs of the laboratory and its customers.</p>
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D. Assumptions

Assumptions are statements taken for granted or accepted as true without proof. Assumptions are made in the absence of fact. List and describe the assumptions made in the decision to charter this project.

<p>As DCLS plans for the development and implementation of a comprehensive LIMS, the following assumptions must be made:</p> <ul style="list-style-type: none"> • DCLS will continue to provide laboratory services <u>at the present level</u> (or at an increased level) in support of a wide variety of local, state and federal agencies and therefore will <u>continue</u> to perform millions of scientific tests annually for emergency response, law enforcement, public health and environmental programs. • A public health emergency will take priority over any activities associated with the LIMS project and could result in project delays. • Grant funding for LIMS development and implementation is secure for the FY'04 grant cycle to deploy Phase I of the LIMS implementation project. • Funding will be available for deployment of subsequent phases. • Funding will be available to support ongoing operation following implementation. • ALL stakeholders will be committed to the successful implementation of the DCLS LIMS. • The Project Team will provide the necessary expertise to meet the objectives of the DCLS LIMS project. • Upon acceptance of their role in the LIMS project, key team members will remain on staff and their workload will remain stable so that they are available to fulfill their commitment to the project. A loss of key team members could result in project delays. • DGS support staff will be available to provide hardware, network and database support to maintain the DCLS LIMS. • DCLS customers will participate in the development of the LIMS and will provide necessary information to benefit from its implementation. • The LIMS will improve DCLS processes, enrich services provided and will not slow the testing/reporting of samples received. • The selected LIMS vendor will provide the products and services to support all

business processes as defined in the Requirements Document.

- Project milestones were established with the assumption that the commercial product can be installed with minimal customization to meet DCLS business needs. A greater level of customization could impact project milestones.

E. Project Description, Scope and Management Milestones

• Project Description

Describe the project approach, specific solution, customer(s), and benefits. The Project Description is located in the Project Proposal, Section C.

DCLS is currently exploring all avenues to procure a comprehensive LIMS and will follow standard system life-cycle approach for its implementation. The implementation of a comprehensive, integrated DCLS LIMS will improve services to numerous state and local customers including: Virginia Department of Health, Agriculture and Consumer Services, Conservation and Recreation, Corrections, Criminal Justice Services, Emergency Services, Fire/Hazmat Programs, Environmental Quality, Game and Inland Fisheries, Labor and Industry and the Virginia Lottery.

The DCLS LIMS will:

- Provide customers with real-time access to sample testing, test results and kit information.
- Provide customers with better tools and reports to evaluate laboratory data.
- Provide enhanced connection to National and International Public Health data bases to track organisms and diseases.
- Reduce report delivery times and expands reporting capability.
- Reduce sample collection, data entry, and analytical errors.
- Provide faster results.
- Provide improved quality of laboratory data.
- Provide improved data security and comply with regulations for maintaining and communicating data using standardized data formats.
- Provide additional web functions under the Web-enabled Government initiatives.

Scope

The Project Scope defines all of the products and services provided by a project, and identifies the limits of the project. In other words, the Project Scope establishes the boundaries of a project. The Project Scope addresses the who, what, where, when, and why of a project.

The DCLS LIMS project will encompass the design, development and implementation of a fully integrated laboratory system. The DCLS LIMS must support all major business processes as defined by the APHL LIMS Requirements Document (published 4/15/03) which includes such functionality as sample accessioning, web access for remote data entry and sample tracking, test scheduling, instrument interfacing, electronic result reporting, kits and inventory tracking, quality assurance functionality, ad hoc report generation and connection to national databases for the tracking of organisms/diseases.

The Project Team will establish a phased implementation plan in which the “public health” modules will be developed in Phase I. This will include such areas as Microbial Reference, Immunology/Virology and Epidemiologic Support. Phase I will also include support modules such as sample accessioning, inventory control and quality assurance/quality control. In Phase II, the team will focus on development of the Environmental modules. This will include such areas as Inorganics/Nonmetals, Organics/Commodities, Metals and Food/ Feed/Fertilizer testing and all chemical terrorism-related analyses. During project planning, detailed scheduling will be established for Phase I. Scheduling for Phase II will follow the completion of phase I.

The Project Team will work closely with the vendor on all aspects of design, development and system testing. Representatives from the Project Team will report regularly to the Steering Committee regarding project status. The Program Manager (Dr. Pearson) must approve/sign-off on completion of all major milestones, prior to moving modules into production.

Summary of Major Management Milestones and Deliverables

Provide a list of Project Management Milestones and Deliverables (see Section E of the Project Proposal Document). This list of deliverables is not the same as the products and services provided, but is specific to management of the project. An example of a Project Management Milestone is the Project Plan Completed.

<i>Event</i>	<i>Estimated Date</i>	<i>Estimated Duration</i>
<i>Project Charter Approved</i>	12/16/03	30 days
<i>Project Plan Completed for Phase I</i>	1/31/04	30 days
<i>Project Plan Approved for Phase I</i>	2/28/04	30 days
<i>Phase I - Project Execution – Started</i>	2/28/04	One year
<i>Phase I - Project Execution Completed</i>	2/28/05	3 months
<i>Phase I - Project Closed Out</i>	5/31/05	

F. Project Authority

Describe the authority of the individual or organization initiating the project, any management constraints, management oversight of the project, and the authority granted to the Project Manager.

1. Authorization

Name the project approval authority that is committing organization resources to the project. Identify the source of this authority. The source of the approval authority often resides in code or policy and is related to the authority of the individual's position or title.

As the Director for the Department of General Services, Jim Roberts has decision-making authority for the DCLS LIMS project approval. DCLS Director, Dr. Jim Pearson will serve as the DCLS LIMS Program Manager. As such he will oversee all phases of the DCLS LIMS project and is responsible for project success and deployment. As the DCLS LIMS Project Sponsor, Willie Andrews will support the LIMS project by insuring availability of resources, insuring that project goals are met, resolving priority conflicts and working closely with the Project Manager.

2. Project Manager

Name the Project Manager and define his or her role and responsibility over the project. Depending on the project's complexities, include how the Project Manager will control matrixes organizations and employees.

As Project Manager, William Eighme will coordinate all project-related activities with DCLS, ISS, Vendor (LimsUSA) and customers. DCLS contacts include stakeholders, customers, lab managers and laboratorians. ISS contact will be coordinated through Rick Davis, Application Development Manager and Project Technical Lead. ISS activities shall include but not be limited to Application Development, hardware, network/internet support, and database support. Vendor interaction will be through a designated Lims USA representative and help desk support.

3. *Oversight*

Describe the Commonwealth or Agency Oversight controls over the project.

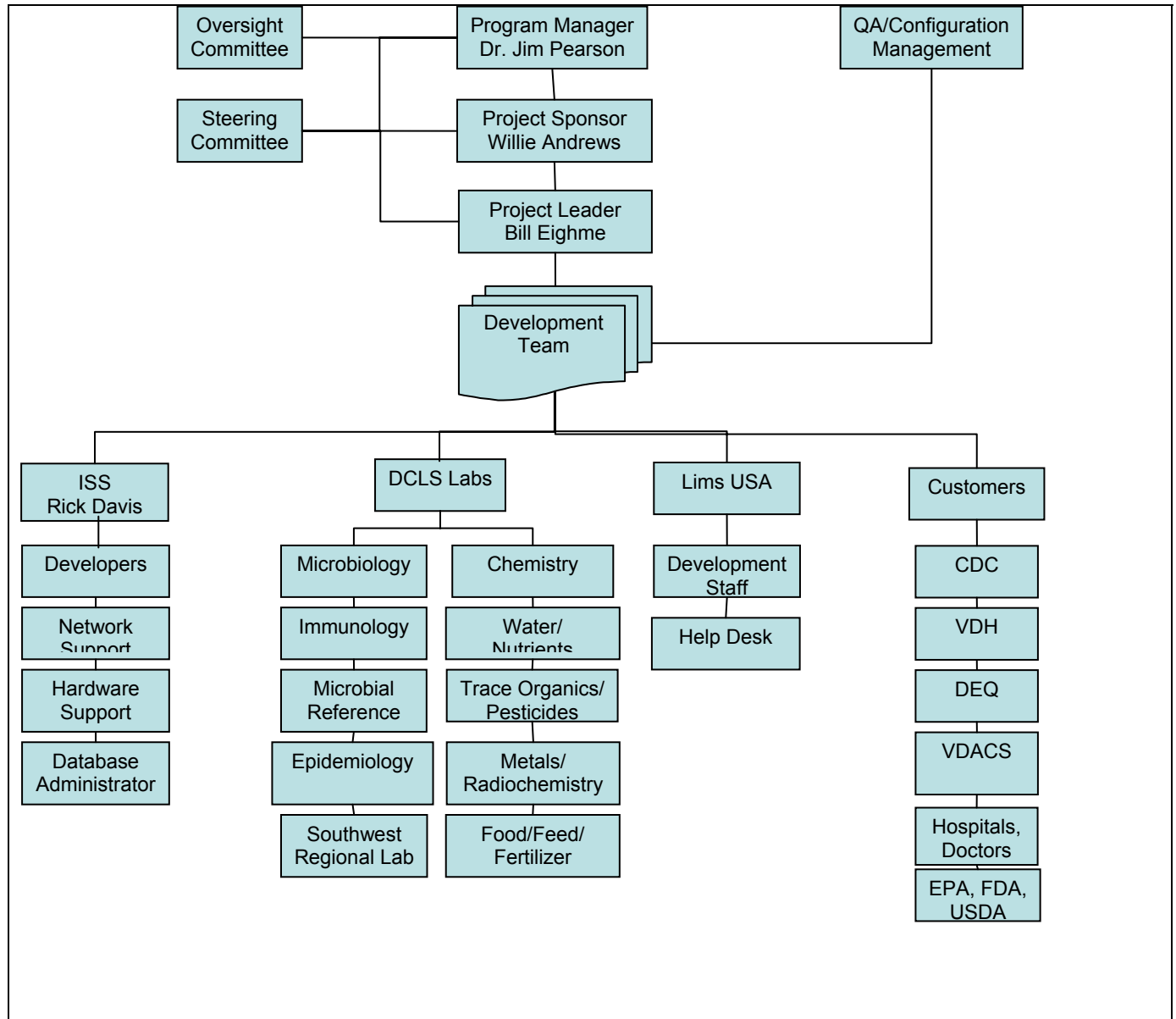
Oversight of the DCLS LIMS project will be the responsibility of Dick Zorn, Deputy Secretary of Administration, Jim Roberts, Director of The Department of General Services and Jim Pearson, Director of the Division of Consolidated Laboratory Services.

In addition, a LIMS Project Steering Committee will meet regularly to monitor project status, insure milestones are met, provide support and approve resources. This committee will include the project's Program Manager (Dr. Jim Pearson), Project Sponsor (Willie Andrews), Project Manager (Bill Eighme), the Technical Project Lead (Rick Davis), ISS Director (Jan Fatorous), Director of Internal Audit (Peggy Ward), and DCLS Business Manager (Tom Flora).

G. Project Organization

1. Project Organization Chart

Provide a graphic depiction of the project team. The graphical representation is a hierarchal diagram of the project organization that begins with the project sponsor and includes the project team and other stakeholders.



2. Organization Description

Describe the type of organization used for the project team, its makeup, and the lines of authority.

The DCLS LIMS Project will utilize a balanced matrix organization due to the fact that various members of the project team will be “borrowed” from their functional units to work on the DCLS LIMS project and then returned once their part of the project has been completed or their skills are no longer required.

The Program Manager (Dr. Jim Pearson) will provide project oversight and project approvals. The Project Sponsor (Willie Andrews) will assign resources, provide project information and provide support to the Project Manager. The Project Sponsor will report ongoing project status to the Program Manager.

The Project Manager (Bill Eighme) will be responsible for assigning priorities, directing the project team and insuring milestones are met. He will report to the Project Sponsor and will share responsibilities with the functional managers for directing the work of individuals assigned to the project.

The Project Manager will coordinate activities with LIMS(USA) team members. All development team members will have access to the Starlims Help Desk.

The Project Manager and Development Team members will interface with customer stakeholders to determine their needs and obtain information regarding LIMS-related issues.

The Technical Project Lead (Rick Davis) will work with the Project Manager to oversee all ISS responsibilities pertaining to Developers, Networking, Hardware, and Database Administrators. Responsibilities include but are not limited to disaster planning, installations/upgrades, maintenance (hardware and database), and backup/recovery.

DCLS Group Managers will work with the Project Manager on their area(s) and designate the appropriate person(s) in their lab group with the knowledge to communicate current workflow, methods, and testing requirements as well as identify opportunities for improvement. Individuals from lab groups and/or The QA/Safety/Training Group will also be a part of the LIMS QA Team and will be involved in acceptance testing.

3. Roles and Responsibilities

Describe, at a minimum, the Roles and Responsibilities of all stakeholders identified in the organizational diagram above. Some stakeholders may exist whom are not part of the formal project team but have roles and responsibilities related to the project. Include these stakeholders' roles and responsibilities also.

The Program Manager, in communication with the Oversight Committee, will be responsible for LIMS Project approval.

The LIMS Project Steering Committee will meet regularly to monitor project status, insure milestones are met, provide support and approve resources.

The Program Sponsor will assign resources and provide support to the Project Manager. The Project Sponsor will prepare project status reports and communicate ongoing project status to the Program Manager.

The Project Manager will work with the Technical Project Lead (ISS) and Development Team members to:

- Comply with VITA project management guidelines
- develop a requirements document
- develop a design document
- prioritize and assign tasks
- determine hardware/db/network configuration
- develop disaster recovery plans
- develop unit test plan
- develop standards for application look, navigation, error handling, etc.

The Project Manager and Development Team members will work with LIMS(USA) to:

- optimize use of Starlims toolset and business rules
- coordinate LIMS(USA) activities with the rest of the development team
- communicate and maintain list of any bugs that might be discovered or Starlims functionality enhancement requests.
- Leverage LIMS(USA) experience

Group Managers or designees must work with the Project Manager and the Quality Assurance Team to:

- document current/proposed workflow
- document every method, test component, unit of measure, list of valid result entries(if applicable)
- develop sample(specimen) test plans
- determine instrument interfaces
- determine barcode requirements
- acceptance test plan

Customers will be called upon to work with the Project Manager and Development Team members will to:

- Streamline sample collection and submission
- Investigate use of barcodes where possible
- Determine reporting requirements
- Determine what submitter information is necessary
- Test interfaces

H. Resources

Identify the initial funding, personnel, and other resources, committed to this project by the project sponsor. Additional resources may be committed upon completion of the detailed project plan.

<i>Resources</i>	<i>Allocation and Source</i>
<i>Funding</i>	Federal funding (grant)
<i>Project Team (Full and Part Time Staff)</i>	\$266,560
<i>Customer Support</i>	\$0
<i>Facilities</i>	\$0
<i>Equipment</i>	\$150,000
<i>Software Tools</i>	\$471,500
<i>Other</i>	Training = \$37,500 Contingency = \$100,000
<i>Total</i>	\$1,025,560

I. Signatures

The Signatures of the people below document approval of the formal Project Charter. The Project Manager is empowered by this charter to proceed with the project as outlined in the charter.

<i>Position/Title</i>	<i>Signature/Printed Name/Title</i>	<i>Date</i>
<i>Proponent Cabinet Secretary (as required)</i>		
<i>Proponent Agency Head</i>		
<i>Project Sponsor (required)</i>		
<i>Program Manager</i>		
<i>Project Manager (required)</i>		
<i>Other Stakeholders as needed</i>		

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